

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of) NOTICE OF PUBLIC HEARING ON
ARM 37.114.701, 37.114.702,) PROPOSED AMENDMENT
37.114.703, 37.114.704, 37.114.705,)
37.114.708, pertaining to)
implementation of HB 158 (2015))
regarding the modernization of)
immunization laws related to school)

TO: All Concerned Persons

1. On August 19, 2015, at 3:30 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on August 12, 2015, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.114.701 DEFINITIONS The following definitions, together with the definitions contained in 20-5-402, MCA, apply throughout this subchapter:

(1) through (5) remain the same.

(6) "DT vaccine" means a vaccine containing a combination of diphtheria and tetanus toxoids ~~for pediatric use.~~

(7) "DTP vaccine" and "DTAP vaccine" mean vaccines containing diphtheria and tetanus toxoids and pertussis (whooping cough) vaccine combined ~~that are recommended for children under seven years of age.~~

(8) remains the same.

(9) "Immunization information system" means a confidential, computerized, population-based system managed and maintained by the department that collects and consolidates vaccination data from vaccine providers.

(9) remains the same, but is renumbered (10).

~~(10)~~ (11) "Montana Certificate of Immunization Form (HES 101)" means the form prescribed by the department as required by 20-5-406, MCA. Copies of the

form may be requested from the Department of Public Health and Human Services, Public Health and Safety Division, Communicable Disease Control and Prevention Bureau, Immunization Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951, telephone: ~~(406)444-4735 or~~ (406)444-5580.

(11) remains the same, but is renumbered (12).

~~(12)~~ (13) "Official parent maintained immunization record" means a standard document electronic or paper record that is distributed maintained by the department, or by another state's principal health agency, or by a healthcare provider to record the immunization status of a child, is designed to be retained and maintained by the parents of that child, and includes the following:

(a) child's legal name;

(b) birthdate;

(c) sex; and

(d) vaccination date (month, day, and year) by vaccine type, or, in the case of a postsecondary record, the month and year of vaccine administration.

~~(a) the child's legal name, birthdate, sex and vaccination date (month, day and year) by vaccine type, except that in a postsecondary school, if only the month and year of administration are listed, the administration date will be considered to be the first day of that month; and~~

~~(b) for each administration of vaccine, the vaccination data must be completed and signed or stamped by the physician or officer of a health department who administered the vaccine or designee of the physician or officer.~~

(13) through (17) remain the same, but are renumbered (14) through (18).

~~(18)~~ (19) "Td vaccine" means a vaccine containing tetanus and diphtheria toxoids and intended for administration to adults and to children seven years of age and older.

(20) "Tdap vaccine" means a vaccine containing tetanus and diphtheria toxoids, and acellular pertussis.

(19) and (20) remain the same, but are renumbered (21) and (22).

(23) "Varicella vaccine" means a vaccine containing a live-attenuated varicella vaccine.

AUTH: 20-5-407, MCA

IMP: 20-5-402, 52-2-703, MCA

37.114.702 GENERAL IMMUNIZATION REQUIREMENTS FOR ALL SCHOOLS

(1) through (3) remain the same.

~~(4) Doses of MMR vaccine, to be acceptable under these rules, must be given no earlier than 12 months of age, and a child who receives a dose prior to 12 months of age must be revaccinated before attending school. Dose two must be separated from dose one by at least 28 days. Vaccine doses given up to four days before the minimum interval or age are counted as valid. Live vaccines not administered at the same visit must be separated by at least four weeks.~~

(5) DTP and DTaP vaccines are not recommended or required to be administered to children seven years of age or older. Documentation of immunity from varicella, measles, mumps, or rubella by laboratory evidence, or

diagnosis/verification of disease by physician, nurse practitioner, or physician's assistant, may be used in lieu of the vaccine requirement.

AUTH: 20-5-407, MCA

IMP: 20-5-403, MCA

37.114.703 REQUIREMENTS FOR ADEQUATE DOCUMENTATION OF IMMUNIZATION STATUS (1) The following are considered adequate documentation of immunization for the purposes of this subchapter, subject to the restriction in (2):

(a) and (b) remain the same.

(c) any official immunization record, if information has been recorded and signed or stamped by a physician, physician's designee, local health officer, or that officer's designee; or an official report from the statewide immunization information system, or a healthcare provider's medical record system;

(d) and (e) remain the same.

(f) the international certificates of vaccination approved by the world health organization; or

~~(g) the conditional enrollment form prescribed by the department;~~

~~(h) documentation of a medical exemption signed by a physician;~~

~~(i) documentation of a religious exemption, signed and notarized at the start of each school year, or, in a postsecondary setting, each year beginning with the date the pupil commences attendance; or~~

(j) remains the same, but is renumbered (g).

(2) remains the same.

(3) The following are considered adequate documentation in lieu of receiving required vaccines:

(a) the conditional enrollment form prescribed by the department;

(b) documentation of a medical exemption signed by a physician;

(c) documentation of immunity from varicella, measles, mumps, or rubella by laboratory evidence or diagnosis/verification of disease by physician, nurse practitioner, or physician's assistant; or

(d) documentation of a religious exemption, signed and notarized at the start of each school year; or in a postsecondary setting, each year beginning with the date the pupil commences attendance.

AUTH: 20-5-407, MCA

IMP: 20-5-402, MCA

37.114.704 REQUIREMENTS FOR UNCONDITIONAL ATTENDANCE AT A PRESCHOOL (1) Before a prospective pupil may attend a Montana preschool, that school must be provided with adequate documentation that the prospective pupil has been immunized in accordance with the following standards:

(a) remains the same.

(b) the prospective pupil must receive one dose of MMR vaccine, administered no earlier than 12 months of age; ~~– A prospective pupil who receives a~~

dose prior to 12 months of age must be revaccinated before attending a preschool; and

(c) one dose of Hib vaccine must be administered on or after the first birthday, unless the prospective pupil is older than 59 months of age; and

(d) the prospective pupil must have received one dose of varicella vaccine, administered no earlier than 12 months of age.

(2) If a prospective pupil is not vaccinated with all of the vaccines required in (1), the prospective pupil ~~must be immediately excluded from the preschool unless the prospective pupil is completely vaccinated, an exemption from a vaccine or vaccines is claimed, or the prospective pupil is enrolled conditionally~~ may be admitted conditionally in accordance with the requirements of ARM 37.114.710.

~~(3) A prospective pupil may attend a preschool with conditional enrollment if:~~

~~(a) the prospective pupil has received at least one dose of each of the vaccines required for the prospective pupil's age;~~

~~(b) a department prescribed form documenting the prospective pupil's conditional immunization status is on file at the preschool, attached to HES 101; and~~

~~(c) the prospective pupil is not past due for the next required dose (as noted on the conditional enrollment form) of the vaccine in question.~~

~~(4) remains the same, but is renumbered (3).~~

~~(5) HES 101 must be completed with adequate documentation provided by the pupil's guardian, copies of which must be attached to HES 101 if the form is completed by daycare or school personnel.~~

~~(6) remains the same, but is renumbered (4).~~

AUTH: 20-5-407, MCA

IMP: 20-5-403, 20-5-406, MCA

37.114.705 REQUIREMENTS FOR UNCONDITIONAL ATTENDANCE AT A SCHOOL OFFERING ANY PORTION OF GRADES KINDERGARTEN THROUGH 12 (1) remains the same.

(2) Vaccines immunizing against diphtheria, pertussis, and tetanus must be administered as follows:

(a) remains the same.

(b) A pupil or prospective pupil seven years old or older who has not completed the requirement in (2)(a) must receive additional doses of Tdap vaccine or Td vaccine to reach a minimum of three doses of any combination of DTP, DTaP, DT or Td. Pertussis vaccine is not required for a pupil seven years of age or older to become current in accordance with the ACIP schedule;

~~(c) Beginning with the 2006-2007 school year, p~~Prior to entering the seventh grade, a pupil must receive a dose of vaccine containing Td Tdap vaccine if the following criteria are met:

~~(i) at least a five year interval must have passed since the pupil's previous doses of DTP, DTaP, DT or Td;~~

~~(ii) (i) the pupil is 11 years of age or older; or~~

~~(iii) (ii) a dose of Td Tdap vaccine was not given to the pupil at seven years of age or older;~~

(d) If a pupil enters the seventh grade before reaching 11 years of age, a booster shot of ~~Td~~ Tdap vaccine must be administered to the pupil as soon as possible after the pupil attains that age, unless the pupil already was administered a dose of ~~Td~~ Tdap vaccine at seven years of age or older;.

~~(e) DT vaccine administered to pupils less than seven years of age is acceptable only if accompanied by a medical exemption that exempts the pupil from pertussis vaccination.~~

(3) remains the same.

(4) ~~Beginning with the 2005-2006 school year, the following~~ A pupils or prospective pupil must have received two doses of live measles, mumps, and rubella vaccine ~~at or after~~ no earlier than 12 months of age, ~~separated by at least one month between doses:~~

~~(a) a pupil entering kindergarten, or, in the case of a school with no kindergarten, first grade; or~~

~~(b) a pupil entering any grade from seventh grade to twelfth grade who has not already received the two required doses.~~

(5) A pupil or prospective pupil must have received two doses of live varicella vaccine no earlier than 12 months of age.

AUTH: 20-5-407, MCA

IMP 20-5-403, 20-5-405, 20-5-406, MCA

37.114.708 DOCUMENTATION OF IMMUNIZATION STATUS OF PERSONS COMMENCING ATTENDANCE IN PRESCHOOL OR KINDERGARTEN THROUGH GRADE 12 (1) remains the same.

(2) HES 101 may be accepted by the school without reference to other adequate documentation if:

(a) sections I and II are completed and signed by a physician, local health department official, ~~or the designee of either,~~ or the form is directly obtained from the immunization information system; and

~~(b) section IV is signed by a physician~~ the pupil claims no exemptions.

(3) If the information required by (1) has not been provided to the school on HES 101:

(a) immunization data must be transferred onto HES 101 from adequate documentation;

(b) sections I and II of HES 101 must be signed and dated by a school official or the official's designee; and

~~(c) beginning with pupils entering a Montana school for the first time during or after the 2005-2006 school year,~~ a copy of the adequate documentation must be attached to HES 101.

AUTH: 20-5-407, MCA

IMP: 20-5-406, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) proposes to amend ARM 37.114.701, 37.114.702, 37.114.703, 37.114.704, 37.114.705, and 37.114.708, which specify the immunizations required for school-age children between preschool and 12th grade, to implement House Bill 158 passed by the 64th Montana Legislature. House Bill 158 generally revises school immunization laws; adds varicella to the list of required immunizations; revises requirements related to the pertussis vaccination; and amends 20-5-403 and 20-5-404, MCA. With the passage of House Bill 158, Montana became the last state to mandate a varicella (chickenpox) vaccine requirement and the 46th state to require a pertussis booster at middle school entry. House Bill 158 changes become effective October 1, 2015.

Substantively, the proposed rule amendments implement new vaccination requirements and use in accordance with national standards established by the Advisory Committee on Immunization Practice (ACIP). Recommendations of ACIP are adopted nationally by the U.S. Centers for Disease Control and Prevention and are considered to be the standard of care for the immunization of children. Based upon experiences in other states, the addition of the varicella vaccine to the required list of immunizations provided in 20-5-403, MCA, for school attendance will reduce the burden of those stated conditions on school populations.

Specifically, the proposed amendments include the following:

ARM 37.114.701

The department is proposing to amend this rule by updating existing definitions to clarify terminology and remove repetitive language from the rule. New definitions are proposed to be added for "immunization information system," which is the department's vaccination data system, "Tdap vaccine," and "varicella vaccine." The addition of the new definitions is necessary as those terms are not defined in statute. The revision of certain existing definitions to remove outdated, repetitive, or superfluous language is necessary because such revisions are consistent with the department's statutory obligations under the administrative procedures act for periodic rule review and for providing clear and understandable rules.

ARM 37.114.702

The department is proposing to amend this rule by revising general immunization requirements for all schools by removing unnecessary and confusing language from the rule. Additionally, recommendations are proposed to be added to align the rule with ACIP recommendations for a four-day grace period relative to established immunization intervals or ages together with providing exemptions for pupils who may not be required to receive a vaccine due to a history of disease. The department has determined through its review of the rule that the amendments are necessary because both the four-day grace period and the history of disease recommendations are standards of care that have not been previously addressed in rule. The addition of the language will make the standard of care official and avoid potential confusion.

ARM 37.114.703

Requirements for documentation are proposed for update by removing outdated terminology. These amendments are necessary for the rule to remain consistent with advancements in medical records technology. Additional language has been proposed and deemed necessary to add a documented history of disease, including the need for varicella protection addressed by House Bill 158, to the list of adequate documentation in lieu of receiving required vaccines.

ARM 37.114.704

The department is proposing to revise rule language for preschool attendance by adding the new varicella requirement for this age group, which is necessary for the department to implement House Bill 158. The department also proposes to remove repetitive language from the rule as conditional attendance requirements are addressed in ARM 37.114.710 in more precise detail.

ARM 37.114.705

The department is proposing to revise rule language for attendance for entry into school grades kindergarten through twelfth grade by adding language to address the new varicella and pertussis requirements under House Bill 158. These amendments are necessary because prior to the addition of the pertussis requirement for middle school, the tetanus, diphtheria, and pertussis requirements did not align with the ACIP recommendations. The proposed text now aligns with the ACIP recommendation and alleviates confusion between school rules and standard of care.

ARM 37.114.708

Consistent with the department's statutory obligations under the administrative procedures act for periodic rule review, the department is proposing changes to the documentation of immunization status by adding language to modernize and align the code with current practices. New rule language is necessary to address the prevailing use of electronic systems for documentation of immunization.

FISCAL IMPACT

The proposed rule changes may immediately affect all parents of students attending Montana schools beginning with the 2015-2016 school year as students may be required to have a doctor's visit and update their vaccination status.

The fiscal impact of this rulemaking implementing House Bill 158 is undetermined at this time because (1) the department can only approximate the number of pupils whose immunizations will need to be brought up to date based on limited vaccination rate data; and (2) of those affected students, the cost of bringing immunizations

current varies on whether the pupil has private insurance, Medicaid, or no insurance coverage at all. Provided, however, the fiscal impact to parents with some form of insurance should be minimal because vaccines are preventative care and fully covered under most insurance. Moreover, the federally funded Vaccines for Children (VFC) program exists to provide vaccines without cost to those who would normally not be vaccinated due to inability to pay.

5. The department intends to adopt these rule amendments effective October 1, 2015.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., August 27, 2015.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 6 above or may be made by completing a request form at any rules hearing held by the department.

9. An electronic copy of this proposal notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of the notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by mail on July 30, 2015.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Nicholas Domitrovich
Nicholas Domitrovich
Rule Reviewer

/s/ Richard H. Oppen
Richard H. Oppen, Director
Public Health and Human Services

Certified to the Secretary of State July 20, 2015.